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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. MICHAEL ARNOLD, and DARRELL CREQUE, Defendants.	No. CR 10-0642 CRB UNITED STATES' OPPOSITION TO DEFENDANT'S MOTION TO DISMISS INDICTMENT

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INTRODUCTION

The defendants' motion to dismiss should be denied because the indictment charges the defendants with all of the essential elements of Controlled Substances Act (CSA) violations using the language of the statute, which is not vague as applied to the defendants' conduct alleged in the indictment. The indictments' allegations, which must be taken as true, assert that the defendants knowingly and intentionally distributed controlled substances that were not authorized by physicians acting in the usual course of professional practice. This language is all that is necessary to state an offense. The defendants' contention that the Ninth Circuit requires "more" is contrary to both circuit and Supreme Court precedent. The defendants' attempt to misconstrue the indictment as charging distribution of controlled substances absent a face-to-face doctor-patient relationship ignores the plain language of the indictment. The indictment clearly alleges that the distribution was "outside the scope of professional practice and not for a legitimate medical purpose." While the absence of physical examinations is one example of how the defendants' illegally distributed drugs, the indictment need not list the theories under which the United States will proceed or the evidence that it will introduce. The indictment does not allege that the defendants failed to engage in any one particular medical practice but instead charges them with distributing drugs in violation of the CSA because its narrow exception to the ban on distributing controlled substances, allowing physicians to authorize distribution for a valid medical purpose in the usual course of professional practice, does not apply to their conduct. As several circuit courts, including the Ninth Circuit, have held, the CSA is not vague as applied to the conduct charged in the indictment. It has been well established for over thirty years that physicians cannot authorize the distribution of drugs unless they are acting in the scope of professional practice. The indictment alleges that the defendants acted "knowingly and intentionally," and this knowledge element is naturally read to encompass all elements of the offense, including that the drugs were distributed "outside the scope of professional practice and not for a legitimate medical purpose." Because the indictment properly charges the defendants with violations of the CSA, the defendants' motion to dismiss should be denied.

BACKGROUND

On August 31, 2010, a grand jury sitting in the Northern District of California returned a thirteen count indictment charging the defendants and nine others with violations of the CSA (21 U.S.C. §§ 841 and 846), and money laundering statutes (18 U.S.C. §§ 1956(h) and 1957), based on their participation in Internet pharmacy operations. *See* Clerk's Record ("CR") 1 (hereinafter "Indictment"). The indictment alleges that defendant Arnold was one of the owners and operators of the Internet pharmacy known as Pitcairn. Indictment ¶ 14. The indictment alleges that defendant Creque was the pharmacist at the fulfillment pharmacy Kwic Fill, Inc. ("Kwic Fill"), that filled orders for various Internet pharmacies, including Pitcairn. *Id.* ¶ 19.

The Indictment charges the defendants with violations of the CSA using the language of the statute. For example, the language of Count Four states:

> Beginning at a time unknown to the grand jury, but no later than May of 2003 and ending in or about April of 2007, both dates being approximately and inclusive, within the Northern District of California an elsewhere, the defendants . . . together with others known and unknown to the grand jury, conspired to distribute, and to possess with intent to distribute, outside the scope of professional practice and not for a legitimate medical purpose, one or more controlled substances, which offense involved substances containing (a) phendimetrazine, a Schedule III controlled substance; (b) diazapam, a Schedule IV controlled substance; (c) phentermine, a Schedule IV controlled substance; and (d) clonazepam, a Schedule IV controlled substance, in violation of Title 21, United States Code, Section 841(a)(1), all in violation of Title 21, United States Code, Sections 846, 841(b)(1)(D) and 841(b)(2).

Indictment ¶ 41. Similarly, the language of Count Five states:

> On or about November 18, 2005, within the Northern District of California and elsewhere, defendants . . . together with others, did knowingly and intentionally distribute, and possess with intent to distribute, outside the scope of professional practice and not for a legitimate medical purpose, one or more controlled substances, which offense involved a substance containing: phentermine, a Schedule IV controlled substance, in violation of Title 21, United States Code, Sections 841(a)(1) and (b)(2).

Indictment ¶ 43.

The Indictment further alleges that the defendants distributed drugs to customers only after those customers provided credit card information and completed a brief on-line questionnaire. Indictment ¶ 14. Customers were not required to submit a valid form of identification or a valid prescription prior to receiving the controlled substances. *Id*. Instead, the customers' questionnaires would be forwarded to a medical doctor, licensed only in Puerto Rico, who approved the customers' orders without conducting a physical examination, obtaining a complete medical history, or confirming the accuracy of the information on the questionnaire. *Id*. ¶ 16. The drug orders were then sent to various fulfillment pharmacies located throughout the United States, including Kwic Fill, where pharmacists, including defendant Creque, filled orders for controlled substances that were not supported by valid prescriptions. *Id*. ¶ 19.

DISCUSSION

A. Federal Rule of Criminal Procedure 12(b)(3).

Defendants have moved to dismiss the indictment pursuant to Federal Rule of Criminal Procedure 12(b)(3)(B), which requires a party to raise before trial a motion alleging a defect in the indictment. When considering a motion for dismissal under Rule 12, the court must accept all of the government's allegations in the indictment as true. Fed. R. Crim. P. 12(2) (precluding pretrial motions that would require a "trial of the general issue"); *United States v. Sampson*, 371 U.S. 75, 78-79 (1962). The indictment should be "(1) read as a whole; (2) read to include facts which are necessarily implied; and (3) construed according to common sense." *United States v. Blinder*, 10 F.3d 1468, 1471 (9th Cir. 1993) (internal quotation omitted). An indictment is sufficient if it: "(1) contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and (2) enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense." *United States v. Lazarenko*, 564 F.3d 1026, 1033 (9th Cir. 2009).

Defendants have filed motions to dismiss the indictment, claiming that their conduct as alleged in the indictment is not illegal under the CSA, that the provisions of the CSA are unconstitutionally vague, and that the indictment fails to allege the appropriate *mens rea* for the

offense. Because the defendants' conduct as alleged in the indictment is illegal under Supreme Court and Ninth Circuit precedent, the CSA is not unconstitutionally vague, and the indictment sufficiently alleges that the defendants' conduct must be "knowing and intentional," defendants' motions should be denied.

B. The Indictment Charges the Defendants with Violating the CSA.

1. The Ninth Circuit Does Not Require "More" Than a Showing that the Defendants Acted "Outside the Scope of Professional Practice and Not for a Legitimate Medical Purpose."

The defendants contend that the indictment fails to charge an offense because it does not allege that the defendants acted as "drug pushers" when they distributed controlled substances to persons who ordered them from defendant Arnold's Internet web sites. Defendant Arnold's Motion to Dismiss ("Def. Mot.") pp. 5-7, 11, 13. The defendants' argument is based on the faulty premise that the Ninth Circuit requires "more" to prove a violation of the CSA than that drugs were distributed "outside the scope of professional practice and not for a valid medical purpose." Def. Mot. pp. 6-7. The defendants' interpretation of the Ninth Circuit's opinion in *United States v. Feingold*, 454 F.3d 1001 (9th Cir. 2006), is both contrary to the holding of that case and to other Ninth Circuit opinions that have affirmed CSA convictions based on a finding that the drugs were not distributed pursuant to a prescription issued for a valid medical purpose by a physician acting within the scope of professional practice. *See, e.g., United States v. Kaplan*, 895 F.2d 618 (9th Cir. 1990); *United States v. Hayes*, 794 F.2d 1348 (9th Cir. 1986); *United States v. Boettjer*, 569 F.2d 1078 (9th Cir. 1978); *United States v. Rosenberg*, 515 F.2d 190 (9th Cir. 1975).

The CSA governs the distribution of controlled substances in the United States. 21 U.S.C. §§ 801-971. Section 841(a)(1) of the CSA provides that: "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally to . . . distribute, or dispense . . . a controlled substance." 21 U.S.C. § 841(a)(1). Section 822 of the CSA authorizes "[p]ersons registered by the Attorney General under this subchapter to . . . distribute . . . controlled substances . . . to the extent authorized by their registration and in conformity with the

other provisions of this subchapter." 21 U.S.C. § 822(b). Registrants, such as licensed and properly registered physicians and pharmacists, may lawfully distribute or dispense controlled substances pursuant to a prescription. 21 U.S.C. § 829(b); 21 C.F.R. § 1300.01(b)(35).

In 1971, the Attorney General promulgated a regulation providing that a controlled substance may be prescribed only "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Specifically, the regulation provides:

> A prescription for a controlled substance to be effective must be issued for a *legitimate medical purpose* by an individual practitioner acting in the *usual course of his professional practice*. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription within the meaning and intent of the section 309 of [the CSA] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a) (emphasis added). As the Supreme Court has noted, this regulation "does little more than restate the terms of the statute itself." *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006) (noting that various sections of the CSA require prescriptions to be supported by a "currently accepted medical use," a "medical purpose," and "issued for a legitimate medical purpose," and that a physician acts as a "practitioner" only where he or she dispenses controlled substances "in the course of professional practice.").

Five years after the regulation was promulgated, the Supreme Court found that the CSA's statutory and regulatory scheme did not amount to a "blanket authorization of all acts by certain persons," and held that, despite registration, "physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice." *United States v. Moore*, 423 U.S. 122, 124 (1975). In *Moore*, the defendant physician wrote 11,169 prescriptions for methadone during a five month period for individuals whom he cursorily examined. *Id*. at 125-26. Moore did not maintain medical records or supervise the administration of the drug, and wrote prescriptions in the quantity that the patient requested. *Id*. at 126. Moore was charged and

convicted of illegal drug distribution under 21 U.S.C. § 841(a)(1). The United States Court of Appeals for the District of Columbia, however, held that Moore could not be convicted under section 841(a) because Congress only intended to subject registered physicians to prosecution under sections 842 and 843 of the act. *Id*.

Reasoning that in enacting the CSA, Congress intended to strengthen existing law enforcement authority in the field of drug abuse, *id*. at 132, the Supreme Court reversed the court of appeals and held that "physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice." *Id*. at 124. The Court reviewed the legislative history of the CSA, and noted that in enacting the CSA, Congress "was concerned with the nature of the drug transaction, rather than the status of the defendant" and intended to make "transactions outside the legitimate distribution chain illegal." *Id*. at 134-35. (citations omitted). Thus, Congress intended to impose "severe criminal penalties" on those "who sold drugs, not for legitimate purposes, but 'primarily for the profits to be derived therefrom.'" *Id*. (further citations omitted).

The Court also found that the provisions of the CSA were unambiguous and declined to construe the statute in favor of the defendant under the rule of lenity. *Id*. at 124, 145. Reviewing the evidence established at trial, the Court held that the evidence was sufficient for the jury to find that the defendant's conduct violated the CSA:

> [The defendant] gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale 'pusher' not as a physician.

Id. at 142-43. In providing this description, the Supreme Court was merely listing the ways in which Moore's conduct had demonstrated that his distribution of drugs "exceeded the bounds of professional practice." *Id*. at 142. The Court stated that the conduct of distributing drugs in violation of the "professional practice" standard was "in practical effect" acting as a "large-scale

'pusher.'" *Id*. The Court did not hold that acting as a "pusher" was a higher or different standard of conduct than acting "outside the scope of professional practice." Rather, the Court analogized a physician who was not prescribing drugs for a "valid medical purpose" to a pusher selling drugs on the street.

Similarly, in *Feingold*, the Ninth Circuit, affirmed the conviction of a physician for illegally distributing controlled substances based on his issuance of prescriptions in "disregard for proper prescribing practices." 454 F.3d at 1004. In its description of Feingold's illegal conduct, the court noted that he had prescribed controlled substances for patients "even though he had never physically examined them and even though he never recorded the medical basis for prescribing these controlled substances in his patients' medical charts." *Id*. He further prescribed controlled substances for persons he knew were recovering drug addicts and persons with whom he had never met. *Id.* Feingold challenged the jury instructions, and the Ninth Circuit held that to prove that Feingold violated the CSA, the United States had to show: "(1) the practitioner distributed controlled substances, (2) that the distribution of those controlled substances was outside the usual course of professional practice and without a legitimate medical purpose, and (3) that the practitioner acted with intent to distribute the drugs and with intent to distribute them outside the course of professional practice." *Id*. at 1108. As the Supreme Court did in *Moore*, the Ninth Circuit equated this standard with acting as a "pusher" rather than a "medical professional," but did not hold or even imply that the "pusher" standard is higher or different than the standard of "outside the course of professional practice" and "not for a valid medical purpose." *Id*. at 1004.

Thus, the indictment validly charges a violation of the CSA by alleging that the defendants (1) distributed controlled substances; (2) that the distribution outside the scope of professional practice and not for a legitimate medical purpose; and (3) that the defendants conduct was knowing and intentional. Neither the statute, the Supreme Court, nor the Ninth Circuit require that anything more be alleged.

It is understandable that the defendants seek to convince the Court that the Ninth Circuit

applies a higher or different standard for exceptions to the CSA than other circuit courts because several of those courts have affirmed convictions of defendants for precisely the conduct with which the defendants are charged here. *See, e.g., United States v. Lovern*, 590 F.3d 1095, 1097-98 (10th Cir. 2009) (pharmacist who distributed drugs for Internet pharmacy operation was properly convicted under CSA); *United States v. Smith*, 573 F.3d 639, 643 (8th Cir. 2009) (online pharmacy operator violated CSA when he facilitated the distribution of drugs that were not authorized by prescriptions issued for a valid medical purposes by a physician acting in the usual course of professional practice); *United States v. Fuchs*, 467 F.3d 889, 896 (5th Cir. 2006) (same); *United States v. Nelson*, 383 F.3d 1227, 1230 (10th Cir. 2004) (doctor who approved drug orders for Internet pharmacy violated the CSA when he acted outside the usual course of professional practice and without a legitimate medical purpose); *see also, United States v. Birbragher*, 576 F.Supp.2d 1000, 1015 (N.D. IA 2008) (declining to dismiss indictment against Internet pharmacy website operators charged with violating the CSA); *United States v. Quinones*, 536 F.Supp.2d 267, 274 (E.D.N.Y. 2008) (same).

The Ninth Circuit has consistently applied the standard set forth by the CSA, as restated in regulation 21 C.F.R. 1306.4 and by the Supreme Court in *Moore*, to affirm the convictions of persons who distribute controlled substances "outside the scope of professional practice and not for a valid medical purpose." *See, e.g., Kaplan*, 895 F.2d at 621; *Boettjer*, 569 F.2d at 1080; *Rosenberg*, 515 F.2d at 199. Moreover, contrary to the defendants' contention, the Ninth Circuit's requirement that the defendant "know" that the distribution is outside the scope of professional practice is consistent with other circuits' interpretation of the CSA. *See Fuchs*, 467 F.3d at 902 (district court did not err by giving a deliberate ignorance instruction to satisfy the "knowledge requirement" that "the manner in which they dispense controlled substances was outside the usual course of professional practice"); *Smith*, 573 F.3d at 649-50 ("good faith" that drugs were issued in usual course of professional practice negates *mens rea* for CSA violation). Thus, the language in the indictment adequately charges the defendants with committing an offense against the United States, and the defendants' motion to dismiss should be denied.

2. The Indictment Need Not Allege the Theory of Proof or Evidence of Guilt.

The defendants also argue that the indictment in this case fails to allege an offense because it charges "only that controlled substances were dispensed pursuant to doctor prescriptions issued after reviews of medical questionnaires instead of in-person examinations." Def. Mot. pp. 3-4. The defendants contend that requiring that a prescription be issued only upon a face-to-face visit with a physician is an impermissible interpretation of the CSA and cannot form the basis for a criminal charge. Def. Mot. 11-12. However, the language cited by the defendants appears nowhere in the indictment, nor does the indictment limit the theory under which the United States will seek to prove that the defendants' conduct was "outside the scope of professional practice and not for a legitimate medical purpose."

An indictment is only required to provide "the essential facts necessary to apprise a defendant of the crime charged" and "need not specify the theories or evidence upon which the government will rely to prove those facts." *United States v. Ely*, 142 F.3d 1113, 1120 (9th Cir. 1998). The indictment in this case does precisely that, alleging that the defendants "did knowingly and intentionally distribute, and possess with intent to distribute, outside the scope of professional practice and not for a legitimate medical purpose, one or more controlled substances. . ." These allegations are taken directly from the words of the statute, which is "generally sufficient" to inform the defendants of the nature of the charges against them. *Id*.

The indictment provides background facts, including examples by which the defendants' conduct was outside the scope of professional practice, so that the defendants are generally apprized of the conduct for which they are being held responsible. One of these examples is that "[a]t no time during the questionnaire review process did Valdivieso or any other approving physician physically examine and obtain a complete medical history from the customers." Indictment ¶ 16. While courts have consistently recognized that the lack of an in-person physical examination is one indication that standards of professional practice were not observed, *see, e.g., Moore*, 423 U.S. at 142-43; *Feingold*, 454 F.3d at 1004; *Kaplan*, 895 F.2d at 620-21; *Rosenberg*, 515 F.2d at 199, this is not the only means by which the defendants are alleged to have acted

outside the scope of professional practice. The indictment does not contain a full recitation of all of the evidence or each of the theories by which the United States will seek to prove its case, nor is it required to do so. The defendants attempt to limit the allegation in the indictment that the defendants acted "outside the scope of professional practice and not for a legitimate medical purpose" to a single method of proof - that the doctors did not conduct physical examinations - and then state that this single theory is insufficient to state an offense. However, nowhere in the Indictment does the United States limit its definition of "outside the scope of professional practice" to this single theory. Instead, the indictment charges the defendants broadly with distributing drugs in violation of the standards set forth in the CSA. *See Quinones*, 536 F.Supp.2d at 271 ("If the means are within the usual scope of professional practice, they are legal; if they are outside that scope, they are illegal."). The role of the indictment is not to prove that the defendants violated those standards. It is merely to allege that they did so. *See Blinder*, 10 F.3d at 1471 ("The sufficiency of an indictment is judged by whether the indictment adequately alleges the elements of the offense and fairly informs the defendant of the charge, not whether the Government can prove its case.") (internal quotation omitted).

As alleged in the indictment, the defendants are charged with violating the CSA by distributing controlled substances outside the scope of professional practice and not for a legitimate medical purpose based on their involvement with various Internet pharmacies. These allegations are sufficient to apprise the defendants of the nature of the charges against them, and no more is required. The defendants will become familiar with the United States' evidence through discovery and with its theories of liability at trial. If, after trial, the defendants wish to attack the United States' evidence or theories as insufficient to sustain a conviction under the CSA, they may do so. However, in a motion to dismiss the indictment filed pursuant to Rule 12, the Court must accept all of the allegations in the indictment as true. The indictment alleges that the defendants distributed controlled substances outside the scope of professional practice and not for a legitimate medical purpose. If those allegations are true, then the defendants have violated the CSA. As the district court stated in *Quinones*, "The government is not trying to

establish a *per se* rule that Internet prescriptions are invalid; rather, it is prosecuting the defendants under the rule established in *Moore* that prescribing drugs outside the usual scope of professional practice is illegal. The government is making no attempt, as in *Gonzales*, to unilaterally define which practice fall outside that scope; rather, it intends to leave that question where it has been for over 30 years - with the jury." 536 F.Supp.2d at 271. Because the indictment properly states an offense under the CSA , the defendants' motion to dismiss the indictment should be denied.[1]

3. The CSA Prohibited the Defendants' Conduct Prior to the Passage of the Ryan Haight Act.

The defendants assert that in 2008, Congress amended the CSA to prohibit individuals from distributing controlled substances over the Internet without an in-person medical examination between the prescriber and patient, and that the amendment helps prove that the pre-amendment CSA did not proscribe their conduct. Def. Mot. p. 8. Congress' passage of this *per se* rule, however, provides no support for defendants' argument that the CSA did not criminalize their conduct as charged in the indictment before the amendment. "[A]n amendment to a statute does not necessarily indicate that the unamended statute meant the opposite." *Hawkins v. United States*. 30 F.3d 1077, 1082 (9th Cir. 1994). Pursuant to *Moore* and its progeny, the CSA clearly proscribed the defendants' conduct of distributing controlled substances outside the usual course of professional practice before the 2008 amendments.

On October 1, 2008, Congress amended the CSA and provided that, except as otherwise authorized, it was unlawful for any person to knowingly and intentionally distribute controlled substances by means of the Internet. 21 U.S.C. § 841(h)(1). In section 841(h)(2), Congress

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[1] Moreover, the allegation that the defendants' conduct was illegal is not contrary to state law. *See* California Bus. & Prof. Code § 2242.1(a) ("No person or entity may prescribe, dispense, or furnish, or cause to be prescribed, dispensed, or furnished, dangerous drugs . . . on the Internet for delivery to any person in this state, without an appropriate prior examination and medical indication . . ."); *Quinones*, 536 F.Supp.2d at 272-73 (concluding that prescribing drugs to patients outside of Puerto Rico is not authorized by that territory's "telemedicine" law).

provided examples of the unlawful distribution by means of the Internet, including writing prescriptions in violation of section 829(e). In that section, Congress defined a "valid prescription" as a prescription issued for a "legitimate medical purpose in the usual course of professional practice" by a "practitioner that has conducted at least 1 in-person medical evaluation of the patient." 21 U.S.C. § 829(e)(1), 2(A). The statute further provided that "nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice." 21 U.S.C. § 829(e)(2)(B)(ii).[2]

The fact that Congress has passed legislation proscribing by a clear-cut, *per se* rule the distribution of controlled substances over the Internet without a face-to-face meeting between patient and doctor does not mean that the same conduct was not illegal under the statute before it was amended. *Quinones*, 536 F. Supp. 2d at 273. "An amendment to an existing statute is not an acknowledgment by Congress that the original statute is invalid. It is common and customary legislative procedure to enact amendments strengthening and clarifying existing laws." *United States v. Tapert*, 625 F.2d 111, 121 (6th Cir. 1980). Moreover, "[t]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *United States v. Price*, 361 U.S. 304, 319 (1960).

In *United States v. Hockings*, 129 F.3d 1069, 1072 (9th Cir. 1997), the Ninth Circuit addressed an analogous situation in which Congress had amended an older statute to more clearly account for recent technological advances. Hockings was charged with interstate transportation of "visual depictions" of minors engaging in sexual activity, after he was found with a computer disk containing images of child pornography. *Hockings*, 129 F.3d at 1070. At the time of his

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[2]In addition to the provisions cited above, the amendments increase regulation of pharmacies seeking to dispense controlled substances via the Internet, require online pharmacies to post certain information on their websites, increase penalties for the distribution of Schedule III and IV controlled substances, and prohibit the use of the Internet to advertise the illegal sale of a controlled substance. 21 U.S.C. §§ 802 (50-56), 823(f), 827(d), 830, 841(b); Ryan Haight Online Pharmacy Consumer Protection Act of 2008, H.R. 6353, 110th Cong. (2008).

offense, the statute defined "visual depiction" to include undeveloped film and videotape, but made no mention of data stored on a disk. *Id*. at 1071. Congress subsequently amended the statutory definition of "visual depiction" to specifically include "data stored on a computer disk." *Id*. Rejecting Hockings' argument that the subsequent amendment demonstrated that the pre-amendment definition did not encompass data stored on a computer disk, the Ninth Circuit found that Congress may amend a statute for any number of reasons, including to clarify existing law, and that the pre-amendment definition did include data on a disk. *Id*. at 1072. The court also rejected Hockings' argument that the statute was void for vagueness. *Id*.

Like the statute in *Hockings*, the 2008 amendment to the CSA simply clarified the CSA's existing application in light of new technology and methods being used to violate it, without any implication that the existing provisions did not already prohibit such conduct. Just as Congress amended the bill in *Hockings* to confirm that the definition of "visual depictions" included computer data - a conclusion that could have been reached even under the pre-amendment statute - Congress amended the CSA to confirm that the CSA prohibits individuals from distributing and conspiring to distribute controlled substances outside the course of professional practice and without a legitimate medical purpose and that a prescription issued without an in-person examination is issued outside the course of professional practice.

Indeed, Congress' use of the phrase "legitimate medical purpose in the usual course of professional practice," in section 829(e), and its explicit pronouncement that "nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice," in section 829(e)(2)(B)(ii), clearly demonstrate that Congress passed the amendment to make what was intended all along even more unmistakenly clear. *United States v. Weaver*, 275 F.3d 1320, 1331 (11th Cir. 2001) (when construing statutes, courts should not look beyond "plain meaning of the statutory language" except when confronted with "absurdity of results."). As the Supreme Court concluded in *Moore*, the legislative history of the CSA demonstrates that physicians who distributed controlled substances outside the course of

professional practice have always fallen within the embrace of section 841(a)(1). Thus, as alleged in the indictment, the defendants' conduct violated the CSA before the Ryan Haight Act was passed in 2008, and their motion to dismiss should be denied.

C. The CSA Is Not Unconstitutionally Vague As Applied to the Defendants' Conduct Alleged in the Indictment.

The defendants also argue that the CSA is unconstitutionally vague as applied to their conduct alleged in the indictment. Def. Mot. pp. 12-13. However, the Ninth Circuit has already addressed this issue and concluded that the statute is not unconstitutionally vague when applied to a physician who distributes drugs "that he does not in good faith believe are for legitimate medical purposes." *Rosenberg*, 515 F.2d at 197. The court noted that the "ease and consistency with which courts have interpreted this language convinces us that it is not vague." *Id*. at 198; *see also United States v. Lovin*, 2008 WL 4492616 at * 5 (S.D. Cal. 2008) (finding that the CSA was not void for vagueness as applied to participants in an Internet pharmacy operation).

Under the Fifth Amendment's Due Process Clause, a criminal statute is void for vagueness if it fails to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute or is so indefinite that it encourages arbitrary and erratic arrests and convictions. *United States v. Williams*, 553 U.S. 285, 304 (2008). However, the vagueness doctrine "is not a principle designed to convert into a constitutional dilemma the practical difficulties in drawing criminal statutes both general enough to take into account a variety of human conduct and sufficiently specific to provide fair warning that certain kinds of conduct are prohibited." *Arnett v. Kennedy*, 416 U.S. 134, 159-60 (1974) (internal citations omitted). A statute is not unconstitutionally vague if it "requires a person to conform his conduct to an imprecise but comprehensible normative standard;" rather it is only unconstitutional where "no standard of conduct is specified at all." *United States v. Moore*, 109 F.3d 1456, 1467 (9th Cir. 1997), *quoting Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489,

495, n.7 (1971)).[3] Due process notice is provided when a statute has been judicially construed to prohibit identical conduct. *Wainwright v. Stone*, 414 U.S. 21, 22-23 (1973).

Defendants' motion ignores the well-settled law that the provisions of the CSA prohibiting the distribution of controlled substances outside the course of professional practice are not unconstitutionally vague, whether applied to doctors, pharmacists or website owners and operators. *See United States v. Hayes*, 595 F.2d 258, 260 (5th Cir. 1978) (rejecting pharmacist's argument that provisions of CSA prohibiting distribution pursuant to prescriptions issued outside the course of professional practice was unconstitutionally vague); *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973) (rejecting physician's argument that provisions of CSA prohibiting distribution outside the course of professional practice were unconstitutionally vague); *Quinones*, 536 F.Supp.2d at 274 (rejecting website owners' argument that provisions of CSA were unconstitutionally vague). The fact that the defendants distributed drugs to customers they found on the Internet as opposed to on the streets does not render their conduct lawful or the CSA constitutionally vague. *Id.* at 271 ("That the moving defendants allegedly carried out their activities through the Internet is of no consequence.").

Since *Moore*, courts have consistently held that physicians, pharmacists and non-registrants, including website operators, could be prosecuted for conspiring to distribute and distributing controlled substances outside the usual course of medical practice and without a legitimate medical purpose and that these standards were not so vague as to deprive defendants of fair warning that their conduct was illegal. *Rosenberg*, 515 F.2d at 197-98; *Collier*, 478 at 272 ("in the usual course of professional practice" language not unconstitutionally vague); *United States v. DeBoer*, 966 F.2d 1066, 1068-69 (6th Cir. 1992) (language of § 841(a)(1) is not void for vagueness because it clearly defines a pharmacist's responsibilities); *United States v. Prejean*, 429 F.Supp.2d 782, 805 (E.D. La. 2006) (rejecting defendants' argument that a lack of

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[3] Because the conduct charged in the indictment does not implicate the defendants' First Amendment rights, the "less stringent requirements" for "cases dealing with purely economic regulations" applies. *Smith v. Goguen*, 415 U.S. 566, 573 n. 10. (1974).

consensus among the medical community regarding what is considered "legitimate medical purpose" rendered statute and regulation void for vagueness); *Quinones*, 536 F.Supp.2d at 274 (E.D.N.Y. 2008) (rejecting void for vagueness argument made by operators of nearly identical internet pharmaceutical operation); *Birbragher*, 576 F.Supp.2d at 1012-15 (same); *United States v. Hernandez*, 2007 WL 291584 at * 9 (S.D. Fla. 2007) (adopted by the district court in 2008 WL 559375 (S.D. Fla. 2008)).

In *Rosenberg*, The Ninth Circuit held that the term "in the course of professional practice" as used in the CSA is not vague and that the statue gives "fair notice" that physicians who prescribe drugs outside of that standard are subject to prosecution. 515 F.2d at 197. Noting that "[t]his language has been in the statute books since 1914 and no one has ever had problems with its interpretation," the court concluded that "[t]he language clearly means that a doctor is not exempt from the statute when he takes actions that he does not in good faith believe are for legitimate medical purposes." *Id*. The Ninth Circuit rejected the defendant's constitutional vagueness challenge concluding that "[t]he ease and consistency with which courts have interpreted this language convinces us that it is not vague." *Id*. at 198. Similarly, in *Hayes*, the Fifth Circuit held that the CSA was not unconstitutionally vague as applied to pharmacists. In that case, the defendant, a registered pharmacist, was convicted of conspiracy to distribute controlled substances for his role in filling prescriptions which he knew were not issued in the usual course of professional practice. 595 F.2d at 261. Analyzing the CSA and accompanying regulation at 21 C.F.R. 1306.04(a), the court held, "[t]hus, a pharmacist may not fill a written order from a practitioner, appearing on its face to be a prescription, if he knows the practitioner issued it in other than the usual course of medical treatment. The regulation gives 'fair notice that certain conduct is proscribed.'" *Id.* at 260 (quoting *Rabe v. Washington*, 405 U.S. 313, 315 (1972)).

Defendants cite no decisions that have held the CSA unconstitutionally vague as applied to doctors, pharmacists, or their co-conspirators in the decades since the statute was enacted, and ignore the binding precedent in this circuit, as well as in other circuits that the CSA is not

unconstitutionally vague. *See Rosenberg*, 515 F.2d at 197-98. The fact that the defendants used the Internet to facilitate their unlawful conduct is irrelevant and does not render the indictment defective. *Birbragher*, 576 F.Supp.2d at 1015.

The issue of whether a prescription has been issued outside the usual course of professional practice and other than for a legitimate medical purpose is an issue of fact to be decided by the jury. *Collier*, 478 F.2d at 272. However, physicians, pharmacists and non-registrants have been charged and convicted under the CSA for engaging in conduct similar to that alleged in the indictment, including 1) issuing prescriptions without first examining the patient,[4] 2) issuing prescriptions for a particular controlled substance the patient either named or described,[5] and 3) failing to keep patient records.[6] Similarly, in September 2004,[7] the United States Court of Appeals for the Tenth Circuit affirmed the conviction of a doctor who participated in a nearly identical internet pharmacy operation. *Nelson*, 383 F.3d 1227. And, several months later, the United States Court of Appeals for the Fifth Circuit reached the identical conclusion in reviewing the conviction of a pharmacist for participation in the same conspiracy. *Fuchs*, 467 F.3d 889. These cases are not an exhaustive list of all the possible ways in which an individual can violate the CSA through illegitimate distribution of prescription

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[4]*See, e.g., Kaplan*, 895 F.2d at 620; *Rosenberg*, 515 F.2d at 192; *accord United States v. Johnson*, 831 F.2d 124, 126-27 (6th Cir. 1987); *United States v. Smurthwaite*, 590 F.2d 889, 890 (10th Cir. 1979); *United States v. Roya*, 574 F.2d 386, 389 (7th Cir. 1978); *United States v. Hooker*, 541 F.2d 300, 304-05 (1st Cir. 1976);.

[5]*See United States v. Rogers*, 609 F.2d 834 (5th Cir. 1980) (sufficient evidence supported conviction where doctor asked patients what medication they wanted, rather than what he thought they needed after examining them); *Hooker*, 541 F.2d at 304-05 (affirming conviction where patient selected drugs and "appellant carried out little more than cursory physical examinations, if any, frequently neglected to inquire as to past medical history, and made little or no exploration of the type of problem a patient allegedly had (which might have served as a basis for determining the propriety of a particular treatment)").

[6]*See United States v. Larson*, 722 F.2d 139, 142 (5th Cir. 1983) (failing to produce records indicates lack of compliance with customary medical practice).

[7]The indictment alleges that the conspiracy continued through 2007.

medication. However, the decisions make clear that the CSA prohibits defendants' conduct as charged in the indictment, and that the CSA is not unconstitutionally vague.[8]

D. The Indictment Adequately Alleges the *Mens Rea* of the Offense.

The defendants assert that the indictment fails to allege the *mens rea* required to violate the CSA. Def. Mot. pp. 14-16. However, because the indictment alleges that the defendants must have acted "knowingly and intentionally," as set forth in the language of the statute and the jury instructions approved by the Ninth Circuit, the indictment is not defective and the defendants' motion should be dismissed. The indictment alleges that the defendants "knowingly and intentionally distributed and possessed with intent to distribute, outside the scope of professional practice and not for a legitimate medical purpose, one or more controlled substances . . . ." Indictment ¶ 43. The Ninth Circuit has concluded that to violate the CSA, a defendant must "knowingly and intentionally" commit each aspect of the offense. The defendant must knowingly "distribute" or "possess with intent to distribute," and the defendant must do this "knowing" that what he distributes or possesses is a "prohibited drug," although he need not necessarily know which one. *See* Ninth Circuit Model Jury Instructions 9.13, 9.15. If the drug is distributed pursuant to a prescription issued by a physician, the defendant must also "knowingly and intentionally" act "outside the course of professional practice." *Feingold*, 454 F.3d at 1008.

"In reviewing the sufficiency of the indictment, a court should consider the challenged count as a whole and should refrain from reading it in a hypertechnical manner. The test for validity is not whether the indictment could have been framed in a more satisfactory manner, but whether it conforms to minimal constitutional standards." *Ely*, 142 F.3d at 1120. In this case the

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[8]As defendants acknowledge, physicians are required to abide by professional standards and rules in their licensing states. During the period of the conspiracy, not only did the American Medical Association (AMA) and the Federation of State Medical Boards (FSMB) issue guidelines addressing professional standards of conduct, but so did the State of California. Not surprisingly, each of those states, the AMA and the FSMB provided that prescribing a controlled substance under the circumstances alleged in the Indictment is outside the course of professional conduct.

indictment alleges that the defendants acted "knowingly and intentionally" and then lists the remaining elements of the offense: (1) distributing and possessing with intent to distribute; (2) outside the scope of professional practice and not for a legitimate medical purpose; and (3) one or more controlled substances.[9] The defendants contend that the phrase "knowingly and intentionally" modifies the first and third elements of the offense, but not the second. Def. Mot. p. 14. This tortured reading of the language in the indictment would require that the reader interpret the phrase "knowingly and intentionally" to apply to the beginning and end of the subsequent clause (distributing and controlled substances) but not the phrase in the middle (outside the scope). The defendants do not contend that the indictment is insufficient for failing to repeat the phrase "knowingly and intentionally" before the final clause "one or more controlled substances," which also must be modified by this phrase, but only that the indictment is insufficient for failing to repeat the *mens rea* before the second clause pertaining to the professional practice standard. The defendants' argument is precisely the type of "hypertechnical" distinction without a difference that does not demonstrate that the commonsense language used in an indictment is constitutionally invalid.

The defendants cite no cases in which an indictment charging violations of the CSA has been held insufficient for failing to repeat the *mens rea* before each element of the offense, even though knowledge that the defendant is both "distributing" and that the substance distributed is a "prohibited" drug is required. Rather, alleging that the defendant knowingly and intentionally distributed a controlled substance is generally deemed sufficient to convey the understanding that the term "knowingly and intentionally" applies to both succeeding elements of the offense. The defendants provide no reason why the language charged in the present indictment should be

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[9] It is debatable whether the "exception" to the statutory scheme that the distribution was outside the scope of professional practice must be alleged in the indictment at all. *See United States v. Polan*, 970 F.2d 1280, 1283 (3d Cir. 1992) (holding that an indictment charging a physician with violating the CSA need not allege that the distribution was outside the normal course because this is an "exception" to the statutory scheme, not an element of the offense.)

interpreted differently. *United States v. Du Bo*, 186 F.3d 1177 (9th Cir. 1999) does not compel a contrary conclusion. In that case, the indictment completely failed to allege the *mens rea* applicable to the crime charged. *Id*. at 1179 (indictment charging the defendant with "unlawfully" affecting interstate commerce and "wrongful" use of force failed to allege essential *mens rea* of "knowingly or wilfully" committing these acts). Here, the required *mens rea* is stated in the indictment and, when read in a commonsense manner, modifies all of the elements that succeed it, including "outside the scope of professional practice and not for a legitimate medical purpose."

CONCLUSION

The defendants' motion to dismiss the Indictment should be denied. The Indictment adequately alleges that the defendants violated the CSA by distributing controlled substances outside the scope of professional practice and not for a legitimate medical purpose. The Indictment need not allege each means by which the defendants committed this crime. Rather, alleging violations in the broad terms of the statute, incorporating all necessary elements, as was done here, is all that is required. Contrary to the defendants' assertion, the Ninth Circuit does not require "more" than the Supreme Court or other circuits for a defendant to violate the CSA by distributing drugs that purport to be authorized by a physician. The allegation that the defendants knowingly and intentionally distributed the drugs outside the scope of professional practice and not for a legitimate medical purpose is all that is required. Because the indictment adequately alleges this offense, the defendants' motion to dismiss should be denied.

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Respectfully submitted,

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/s

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